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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,724

09/25/2003

W. Edward Robinson JR.

UCI-12094

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72960

7590

02/05/2009

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EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

02/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/672,724	Applicant(s) ROBINSON ET AL.	
	Examiner Benjamin Packard	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 9/30/08, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – Scope of Enablement

Claims 28-29 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while possibly being enabled for synergistic effect of L-chicoric acid in combination with zidovudine, dideoxycytidine, or 2',3'-dideoxyinosine when used to treat the two HIV strains, HIV_{NL4-3 M185V} and HIV_{NL4-3 JF26/A7}, does not reasonably provide enablement for the broader synergistic therapeutic effect of where integrase inhibitors are used, generally.

This rejection is maintained.

Applicants assert this amendment has overcome the enablement rejection where the specific reverse transcriptase inhibitors were included.

Examiner notes that claim 28 requires a synergistic therapeutic effect on said patient and such claims are routinely subjected to heightened scrutiny by the courts. Where synergy is the unexpected supper-additive result by definition, the enablement of what appears to be three combinations is not sufficient to enable the entire scope of the claim, where integrase inhibitors are claimed generally. This is especially true given the specification only used L-chicoric acid as the sole integrase inhibitor. Claims drawn to

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(unexpectedly) synergistic combinations of known ingredients must be factually supported by data commensurate in scope with the claims. See, In re Kollman, 201 USPQ 193 (C.C.P.A. 1979). (The court affirming a 103 rejection of a claim containing the word “synergistic”, because the claims were not commensurate in scope with the showing of unexpected results, other than at 1:1 ratio for certain specific combinations). Examiner notes that treatment of HIV is high unpredictable, certainly more so than the herbicide treatments at issue in In re Kollman.

Claim Rejections - 35 USC § 103

Claims 28-29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Dombrowaki et al (US 5,759,842 filed 24 Oct 1996 and issued 2 June 1998) in view of Bell (US 5,663,161, filed 2/17/1995 and issued 10/2/1997).

Applicants assert Bell does not teach administering AZT and an integrase inhibitor to an AZT resistant patient, where when a patient is AZT resistant there would be no motivation to continue administering AZT.

Examiner notes that the instant claims are not directed to “AZT resistant” patients, but claim 28 is directed to “HIV infections that are at least partially resistant to treatment by a reverse transcriptase inhibitor” and claim 29 is directed to “said HIV infection is highly resistant to treatment by said reverse transcriptase inhibitor.” Where some sensitivity to a drug exists, one of ordinary skill in the art would still be motivated to administer multiple inhibitors, including the drug which is partially resistant. As such, Dombrowaki et al was cited to show the various compounds used to treat HIV strains

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and Bell provides motivation to combine drugs which treat HIV throughout the lifetime of the virus and through different mechanisms (see Example 3) as a means of maximizing the effect of the treatment, including HIV strains which are partially resistant to AZT.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612